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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,599	07/02/2003	Richard Rox Anderson	101537-0038	4834
21125	7590	04/04/2008	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				BHATIA, AARTI
3763		ART UNIT		PAPER NUMBER
			NOTIFICATION DATE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/612,599	ANDERSON, RICHARD ROX	
	Examiner	Art Unit	
	AARTI BHATIA	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2.05.2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2.12.2007, 12.04.2007</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,183,773 in view of U.S. Patent No. 5,445,611 to Eppstein et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims recite the obvious use of iontophoretic delivery of an active material to infiltrate into spaces in the skin as been shown to be obvious by Eppstein.

3. Claims 1-16 are rejected on the ground of nonstatutory double patenting over claims 1-7 of U. S. Patent No. 6,600,951 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,089 to Tankovich et al in view of U.S. Patent No. 5,445,611 to Eppstein et al.

Tankovich discloses a method for treating a sebaceous gland disorder comprising the steps of a) topically applying an energy activatable material to a section of skin afflicted with a sebaceous gland disorder (column 3, lines 46-48), wherein said material is activated by energy which penetrates outer layers of epidermis, b) causing a sufficient amount of said material to infiltrate into spaces in said skin using ultrasound (column 1, lines 51-55), said sufficient amount of material preferentially accumulating in at least one sebaceous gland relative to interstitial tissue (column 6, lines 23-25); and c) exposing said section of skin to energy sufficient to cause said material to become photochemically or photothermally activated, thereby treating said sebaceous gland disorder by causing a decrease in sebum production (column 6, lines 25-37).

Tankovich fails to teach iontophoretically treating the energy activatable material to cause it to sufficiently penetrate the skin.

Eppstein teaches a method of enhancing transdermal delivery of a drug or dye, and enhancing the permeability of the skin to the solution by means of applying ultrasound or iontophoresis (column 1, line 42-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the ultrasound of Tankovich with the iontophoresis of Eppstein, as they were well known equivalents and iontophoresis was a proven means of effectively enhancing depth of permeation of a topically applied drug solution.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich and Eppstein as applied to claim 1 above, and further in view of U.S. Patent No. 5,633,275 to Mori et al or U.S. Pub No. 2002/0087205 to Chen.

Tankovich and Eppstein disclose the method of claim 1, but teach wherein exposing said section of skin with sufficient energy will result in fragmentation or vaporization of photochemically or photothermally activated material.

Both Mori and Chen teach a photochemically activated material which when exposed to a laser does not substantially result in fragmentation or vaporization.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the carbon solution of Tankovich with a photochemically activated material as taught by Mori, which when exposed to a laser does not substantially result in fragmentation or vaporization, to activate the drug that has been urged into the sebaceous glands.

Response to Arguments

8. Applicant's arguments filed 2/05/2007 have been fully considered but they are not persuasive.

9. The Examiner has withdrawn the objections to the drawings, specification, and claims after review of the Applicant's amendments.

10. The Applicant argues that Tankovich does not discuss preferentially accumulating energy activatable material into the sebaceous gland relative to the interstitial tissue.

11. The Examiner disagrees. Tankovich states: "The carbon solution [energy activatable material] described in the preceeding section is applied and caused to infiltrate into the duct leading to the sebaceous glands as shown in FIG. 5A" (column 6, lines 22-25). The process described by Tankovich is directed to the treatment of acne (column 6, line17).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763